

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GENE DIPOTO

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Serial No.: 10/693,815

Examiner: ANURADHA RAMANA

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Group Art Unit: 3733

Docket No.: 1291.1143101

Customer No.: 28075

Title: METHODS AND APPARATUS FOR STABILIZING THE SPINE
THROUGH AN ACCESS DEVICE

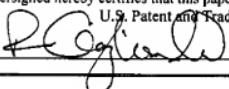
PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP: AF
Commissioner for Patents
P.O. Box 1450
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CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the
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By



Name: Rachel Gagliardi

Dear Sir:

This response is being filed in response to the Advisory Action mailed October 15, 2008 and the Office Action of the Examiner mailed July 8, 2008, with a shortened statutory period set to expire on October 8, 2008. Applicants hereby request a one month extension of time. Please charge the appropriate fee and any additional fees or credit overpayment to Deposit Account No. 50-0413.

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 17, 19-22, 29-31, 34, and 36-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zucherman et al. (U.S. Patent No. 6,074,390). Applicants submit that this rejection is made in error. Applicants note that independent claims 17 and 19 recite methods, setting forth specific steps. Applicants submit that Zucherman et al. do not appear to teach each and every element *as set forth in the claims* 17 and 19, and, therefore, cannot anticipate claims 17 and 19. As an initial point, Applicants note the Examiner acknowledges,

in the rejection under 35 U.S.C. §103, that Zucherman et al. fail to teach a single access device or cannula having an expandable distal end. Applicants submit that the Examiner's inclusion of a separate obviousness rejection clearly indicates the acknowledgement that Zucherman et al. fail to meet the requirements for an anticipation rejection. This rejection is thus made in error.

Further, Zucherman et al. do not appear to teach at least the limitation of "expanding the distal portion of said access device from a first configuration to a second configuration." In contrast, the Examiner asserts on page 5 of the final Office Action "that expanding the access device from a first configuration to a second configuration, does not preclude the use of additional devices placed over the access device, followed by removal of the access device resulting in an enlarged cross section." In the Advisory Action the Examiner states, "it is the Examiner's position that Zucherman et al. disclose the limitation, 'expanding the distal portion of said access device from a first configuration to a second configuration..' for reasons clearly explained in the previous office action." Applicant respectfully disagrees and believes that the Examiner mischaracterizes both claims 17 and 19 and the Zucherman et al. reference.

As to mischaracterizing claims 17 and 19, the claims recite "expanding the distal portion of said access device . . ." As Examiner is likely aware, when interpreting claim language the words of the "claim must be given their plain meaning unless **>the plain meaning is inconsistent with< the specification." *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (MPEP § 2111.01). Applicants submit that the plain meaning of "expanding the distal portion of said access device" clearly involves exactly the action described, e.g., the distal portion of the access device is expanded. Applicants submit that one of ordinary skill in the art would not interpret this claim language as reciting the identical steps of inserting successively larger fixed diameter cannulas into an incision to expand the skin opening, as taught by Zucherman et al. Zucherman et al. teach, at column 9, lines 48-57:

Further, a plurality of cannula can be used instead of one, with each cannula being slightly bigger than one before. In the method of the invention, the *first smaller cannula would be inserted followed by successively larger cannula being place over the previous smaller cannula. The smaller cannula would then be withdrawn from the center of the larger cannula.* Once the largest cannula is in place, and the opening of the skin accordingly expanded,

the implant, which is accommodated by only the larger cannula, is inserted through the larger cannula and into position.

Emphasis added. The Zucherman et al. method appears to teach expanding the opening of the skin, but does not appear to teach or suggest “expanding the distal portion of said access device.” None of the cannula taught by Zucherman et al. appear to be structured to have a distal portion thereof expanded. Applicants submit that the steps of inserting successively larger diameter cannula into an incision, while expanding the incision, cannot be deemed to be the identical method step as “expanding the distal portion of said access device from a first configuration to a second configuration”, as recited in independent claims 17 and 19. Clearly, Zucherman et al. do not teach at least this limitation and therefore do not anticipate claims 17 and 19.

Also, Zucherman et al. do not appear to teach the limitation of “the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of the two adjacent vertebrae”, as recited in claim 17. The device taught by Zucherman et al. does not appear to *extend across* at least a portion of the two adjacent vertebrae, but rather appears to be *inserted between* two adjacent vertebrae. (see Figs. 39-40; column 9, lines 43-47). Zucherman et al. fail to teach the identical method steps recited in independent claims 17 and 19, thus the reliance on Zucherman et al. as anticipating the claims is in error. As claims 20-22, 29-31, 34, and 36-38 depend from claim 19 and include additional limitations, they are also believed patentable over Zucherman et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 17, 19-22, 29-31, 34, and 36-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zucherman et al. (U.S. Patent No. 6,074,390) in view of Davison et al. (U.S. Patent No. 6,187,000). Applicants submit that this rejection is made in error.

As the Examiner is likely aware, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (MPEP § 2143.01 IV). If one were to modify Zucherman et al. according to Davison et al., the principle of operation of Zucherman et al. would change. The Zucherman et al. device appears to narrow towards its

nose end (266) so that the cannula itself may be inserted between the vertebra: “[t]he cannula 258 is somewhat conical in shape with the nose end 266 being somewhat smaller than the distal end 268 in order to effect the *insertion of the cannula into the space between the spinous processes.*” (column 9, lines 43-47) (emphasis added). On the other hand, the Davison et al. device appears broader to provide “a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula.” (column 4, lines 39-42). Modifying Zucherman et al. according to Davison et al. would appear to render the Zucherman et al. device unsuitable for its intended purpose. Applicants submit that there is no motivation for one of ordinary skill in the art to make such a modification, and that Zucherman et al. actually teach away from any combination with Davison et al.

Further, Zucherman et al. already teach using multiple fixed diameter cannula to expand the surgical site, thus there is no motivation for one of ordinary skill in the art to add the device of Davison et al. or modify the device of Zucherman et al. according to Davison et al. to essentially achieve the same result as that already taught by Zucherman et al. Such a modification would appear to be redundant at best. Applicants submit that the lack of any motivation for modifying Zucherman et al. with Davison et al. and the apparent non-functioning of such a modified device suggests that the only motivation for combining Zucherman et al. and Davison et al. is found in Applicants’ own specification, which is an error. For at least the foregoing reasons, Applicant respectfully asserts that a *prima facie* case for obviousness has not been made. Applicant believes that claims 17, 19-22, 29-31, 34, and 36-38 are patentable over Zucherman et al. in view of Davison et al. Withdrawal of the rejection is respectfully requested.

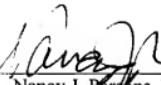
It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his attorney,

Date: 11/7/08



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